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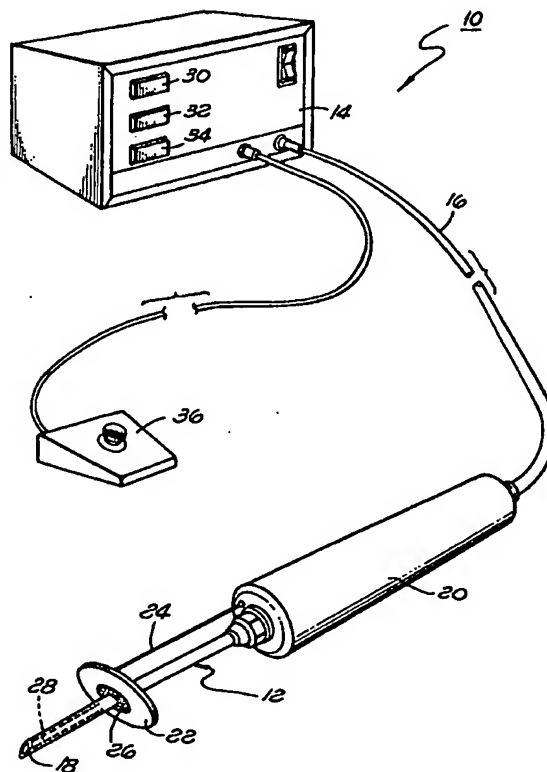
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(54) Title: A RADIO FREQUENCY DEVICE FOR THE TREATMENT OF GLAUCOMA

(57) Abstract

An apparatus and method for treating glaucoma includes a probe (20) that is coupled to a radio frequency generator (14). The probe (20) has a tip (18) that is inserted into the cornea and a stop (22) that limits the insertion depth of the tip (18). The stop (22) also provides a return ground path for the electrical system. Glaucoma is treated by creating an incision in the sclera, inserting the tip (18) through the incision, and into the trabecular meshwork. The electrical energy heats and shrinks the tissue, and opens the trabecular meshwork to increase the flow of aqueous humor from the anterior chamber of the eye.



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A RADIO FREQUENCY DEVICE FOR THE TREATMENT OF GLAUCOMA

5 BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

The present invention relates to an apparatus
10 and method for treating glaucoma.

2. DESCRIPTION OF RELATED ART

The eye contains an internal fluid system
15 which circulates aqueous humor from the anterior
chamber to the bloodstream. Approximately 90% of
the aqueous humor leaves the anterior chamber
through the trabecular meshwork and into Schlemm's
canal. The remaining aqueous humor exits the
20 anterior chamber through uveoscleral pathways.

The flow aqueous humor may be reduced by a
blockage of the trabecular humor. Such a
condition is commonly referred to as open-angle
glaucoma. Glaucoma increases the internal eye
25 pressure and may cause damage to the optic nerve.

There have been developed laser techniques
that open the trabecular meshwork and increase the
flow of aqueous humor from the anterior chamber.
Laser techniques require laser equipment that is
30 relatively expensive. Additionally, the surgeon
must manipulate the ocular lens and the direction
of the laser beam during the procedure. It has
also been found that multiple laser applications
may be required to successfully treat the glaucoma
35 condition.

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There has been developed a technique to shunt the flow of aqueous humor. Glaucoma shunts include a tube and a reservoir that is placed into the anterior chamber of the eye. It has been
5 found that the tubes will clog or fail for a variety of reasons.

There are also many type of drugs used to treat glaucoma. The drugs must be administered on a regular basis and may have unfavorable side
10 effects. Additionally, it has been found that patients may build up a resistance to the drug.

It would be desirable to provide an apparatus and technique for treating glaucoma that is effective and relatively inexpensive to perform.
15

SUMMARY OF THE INVENTION

The present invention is an apparatus and method for treating glaucoma. The apparatus
20 includes a probe that is coupled to a radio frequency (RF) electrical generator. The probe has a tip that is inserted into the cornea and a stop that limits the insertion depth of the tip. The stop also provides a return ground path for
25 the electrical system. Glaucoma is treated by initially creating an incision in the sclera of the cornea. The tip is inserted through the incision into the trabecular meshwork of the cornea. Electrical energy is provided to the
30 tissue of the trabecular meshwork through the probe. The electrical energy heats and shrinks the tissue. Shrinking the tissue opens the trabecular meshwork and increases the flow of aqueous humor from the anterior chamber of the
35 eye.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a system of the present invention;

5 Figure 2 is a cross-sectional view of a cornea with an incision in the sclera;

Figure 3 is a cross-sectional view of the cornea with a probe inserted through the incision and into the trabecular meshwork of the cornea.

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DETAILED DESCRIPTION OF THE INVENTION

Referring to the drawings more particularly by reference numbers, Figure 1 shows a system 10 of the present invention. In general the present invention is a radio frequency (RF) device that is used to treat glaucoma conditions in an eye.

The system 10 includes a probe 12 that is electrically coupled to an RF generator 14 by a wire 16. The distal end of the probe 12 has a tip 18 that is inserted into a cornea. The proximal end of the probe 12 is typically attached to a handpiece 20 that can be held by a surgeon. The handpiece 20 preferably contains a connector that allows the probe 12 to be replaced for each procedure.

The probe 12 has a stop 22 that is attached to the tip 18. The stop 22 limits the insertion depth of the tip 18 so that the surgeon does not inadvertently damage the eye. The stop 22 is connected to a lead 24 that is coupled to electrical ground. The stop 22 and lead 24 provide a return path for the electrical current that flows through the tip 18 and the tissue of the cornea. Although a wire lead 24 is shown and described, it is to be understood that the stop 22

may be electrically connected to a conductive grounded portion of the probe tip. In the preferred embodiment, the stop 22 is separated from the tip 18 by a dielectric spacer 26 that prevents a localized flow of current and generation of heat on the outer surface of the cornea. Additionally, although a bipolar probe is shown and described, the procedure of the present invention may be performed with a monopolar probe.

5 The tip 18 may be constructed as a stainless steel cannula which has an inner channel 28 that allows a drug to be introduced to a cornea. The drug may inhibit tissue growth to maintain the passages created by the present procedure.

10 The RF generator 14 provides electrical energy to the probe 12 to heat and shrink tissue of the cornea. The RF energy can be provided in a continuous mode or a pulse mode. The generator 14 may have console settings 30, 32 and 34 that allow the surgeon to vary the frequency, pulse rate and time duration of energy per application, respectively. The application of electrical energy from the generator 14 to the probe 12 may be controlled by a foot pedal 36 that can be manipulated by the surgeon.

15 Referring to Figure 2, a procedure is performed by initially creating an incision 38 into the sclera 40 of a cornea 42. The cornea 42 has a trabecular meshwork 44 located adjacent to the sclera 40 at the base of the iris 46. The iris 46 is located adjacent to a lens 48 in an anterior chamber 50 of the cornea 42. Aqueous humor flows from the anterior chamber 50 to Schlemm's canal 52. In a cornea with an open-angle glaucoma condition the trabecular meshwork 44 is blocked to inhibit the flow of aqueous

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humor. The reduction in flow increases the fluid pressure within the cornea 42. The increase in fluid pressure may damage the optic nerve (not shown).

5 As shown in Figure 3, the tip 18 is inserted through the incision 38 and into the trabecular meshwork 44. The stop 22 limits the insertion depth of the tip 18 so that the probe 12 does not further penetrate and damage the eye. RF
10 electrical energy is supplied to the tissue of the trabecular meshwork 44 through the probe tip 18. The electrical energy flows through the tissue and into the stop 22. The stop 22 provides a return path that reduces the impedance of the "circuit"
15 through the probe 12 and the cornea 42.

The electrical energy creates heat in the tissue of the trabecular meshwork 44. The heat shrinks the tissue to open and/or create passages in the trabecular meshwork 44. The passages
20 increase the flow of aqueous humor from the anterior chamber 50 and reduce the internal fluid pressure within the cornea 42. A drug or compound may be introduced to the trabecular meshwork 44 to inhibit tissue growth and maintain the openings of
25 the passages. The drug may be introduced through the probe 12 or through a separate cannula.

While certain exemplary embodiments have been described and shown in the accompanying drawings, it is to be understood that such embodiments are
30 merely illustrative of and not restrictive on the broad invention, and that this invention not be limited to the specific constructions and arrangements shown and described, since various other modifications may occur to those ordinarily
35 skilled in the art.

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What is claimed is:

1. A probe that is coupled to an electrical generator and which can be inserted into a tissue, comprising:

- 5 a tip that is electrically coupled to the electrical generator and which has a distal end that is inserted into the tissue,
 a stop that is attached to said tip to limit the insertion of said tip into the tissue; and,
10 a ground lead that is attached to said stop.

2. The probe as recited in claim 1, further comprising a handpiece that is coupled to said tip.

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3. The probe as recited in claim 1, wherein said tip has an inner channel.

4. The probe as recited in claim 1, further comprising a dielectric spacer which separates
20 said stop from said tip.

5. A system that can apply energy to a tissue, comprising:

- 25 a tip which has a distal end that is inserted into the tissue,
 a stop that is attached to said tip to limit the insertion of said tip into the tissue;
 a ground lead that is attached to said stop;
30 and,
 an electrical generator that is coupled to said tip to provide electrical energy to said tip and the tissue.

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6. The system as recited in claim 5, further comprising a handpiece that is coupled to said tip.

5 7. The system as recited in claim 5, wherein said tip has an inner channel.

8. The system as recited in claim 5, further comprising a dielectric spacer which separates
10 said stop from said tip.

9. The system as recited in claim 5, further comprising a foot pedal which controls the electrical energy provided to said tip.

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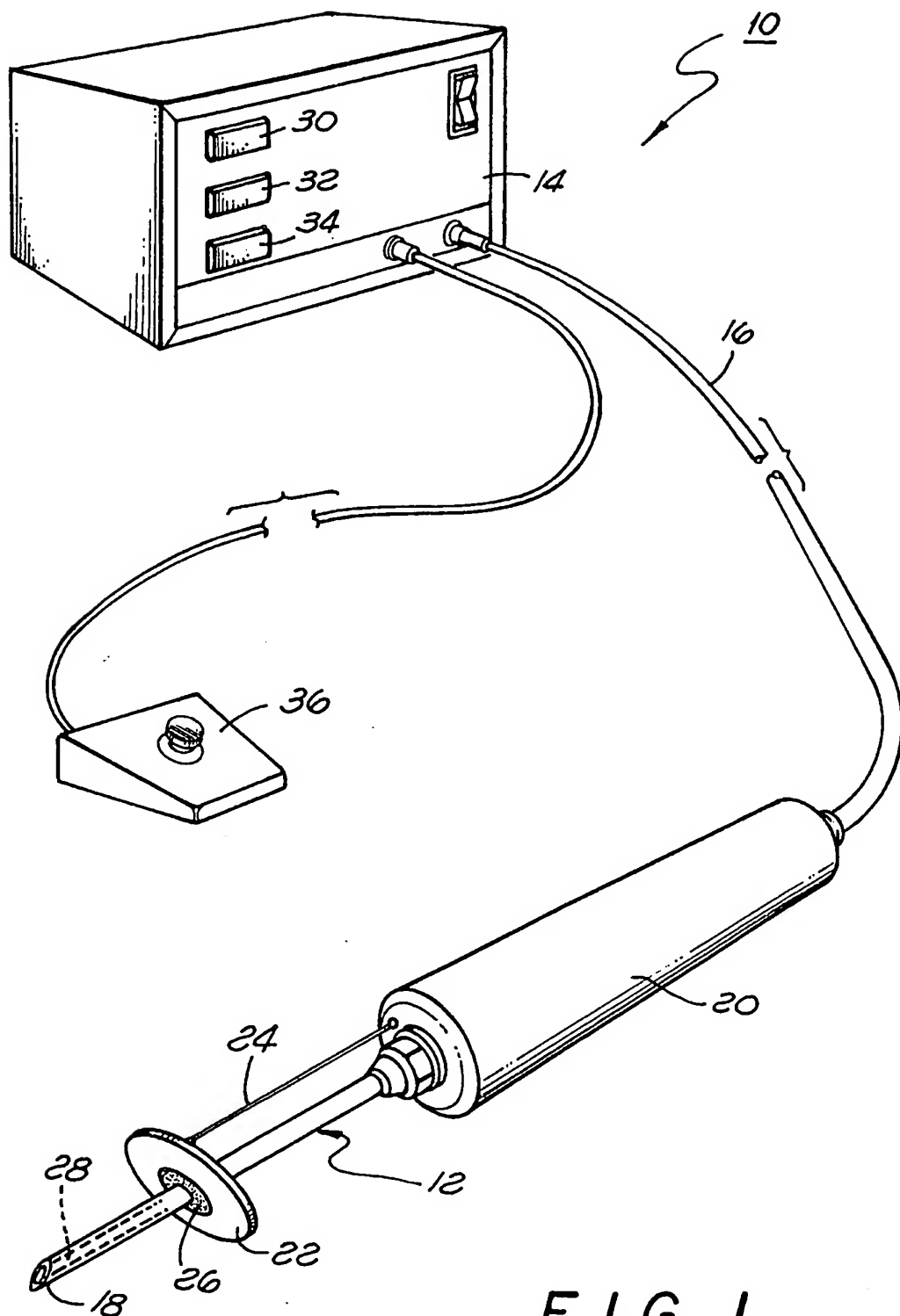
10. A method for enhancing aqueous flow within a cornea which has a sclera and a trabecular meshwork, comprising the steps of:

- 20 a) creating an incision in the sclera;
 b) inserting a probe through the incision and into the trabecular meshwork; and,
 c) applying energy to the trabecular meshwork through said probe.

25 11. The method as recited in claim 10, wherein the electrical energy is at a radio frequency.

12. The method as recited in claim 11,
30 wherein the electrical energy flows through the cornea and into a stop of said probe.

13. The method as recited in claim 10,
 wherein said probe is inserted through the
35 incision until a stop of said probe engages the cornea.



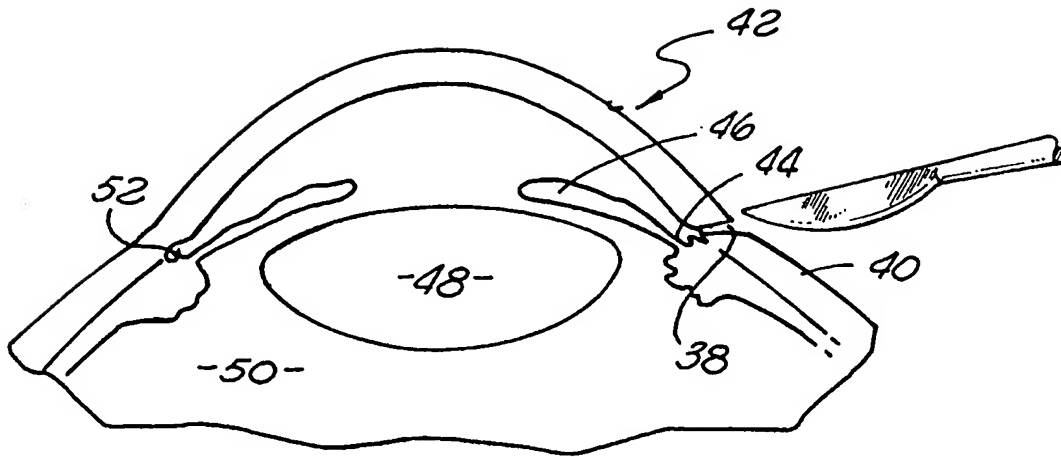


FIG. 2

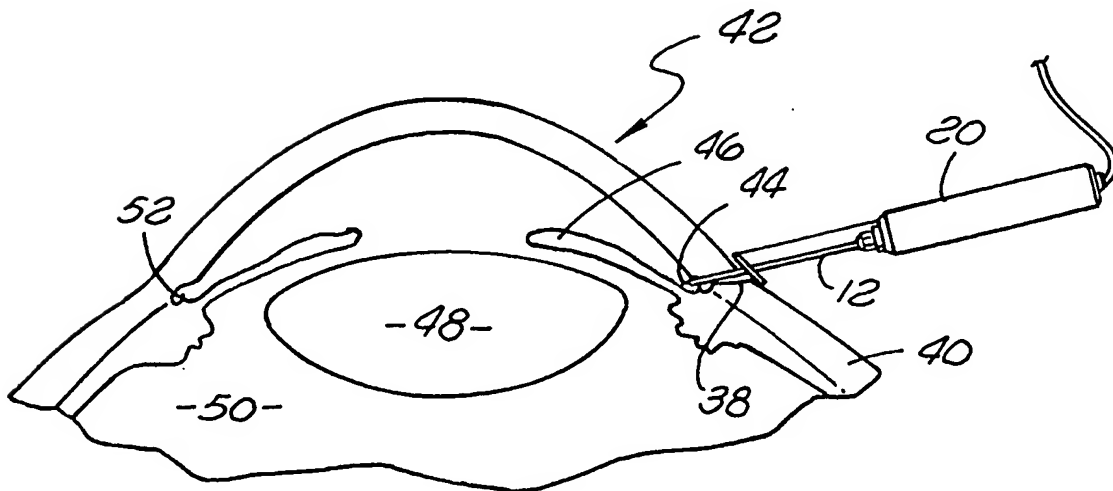


FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/00388

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/36
US CL :606/45

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/898; 606/41, 42, 45-50

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,403,311 A (ABELE et al) 04 April 1995, whole document, and Figs. 2, 4 and 5.	1-8 ----- 9
X --- Y	US 5,330,470 A (HAGEN) 19 July 1994, whole document, and Fig. 2.	1, 2, 4-6, 8, 9 ----- 9
X	US 4,674,499 A (PAO) 23 June 1987, whole document.	10-13
A	US 4,301,802 A (POLER) 24 November 1981, whole document.	1-13

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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